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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,501	07/24/2003	Anand C. Burman	U 014366-2	1973
7590	12/12/2005		EXAMINER	
Ladas & Parry 26 West 61 Street New York, NY 10023			THERKORN, ERNEST G	
			ART UNIT	PAPER NUMBER
			1723	

DATE MAILED: 12/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/626,501	BURMAN ET AL.	
	Examiner	Art Unit	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 28 November 2005.
- 2a) This action is **FINAL**.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 1-15 and 18-20 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 16,17 and 21-30 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

Claims 25-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 25-30 are dependent upon non-elected claims. As such, they are considered to be indefinite.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 16, 17, and 21-30 are rejected under 35 U.S.C. 102(B) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over each of Agharkar (U.S. Patent No. 5,504,102), Anevski (U.S. Patent No. 6,388,122), and Zhang (WO 01/52838). The claims are considered to read on each of Agharkar (U.S. Patent No. 5,504,102), Anevski (U.S. Patent No. 6,388,122), and Zhang (WO 01/52838). However, if a difference exists between the claims and each of Agharkar (U.S. Patent No. 5,504,102), Anevski (U.S. Patent No. 6,388,122), and Zhang (WO 01/52838), it would

reside in optimizing the components of each of Agharkar (U.S. Patent No. 5,504,102), Anevski (U.S. Patent No. 6,388,122), and Zhang (WO 01/52838). It would have been obvious to optimize the components of each of Agharkar (U.S. Patent No. 5,504,102), Anevski (U.S. Patent No. 6,388,122), and Zhang (WO 01/52838) to enhance purity.

The remarks urge that the amendment to claim 21 renders the rejection of claims 21-30 moot. However, claims 25-30 are still dependent upon non-elected claims. As such, they are still considered to be indefinite.

The remarks urge that the product by process claims have been shown to be different from each of Agharkar (U.S. Patent No. 5,504,102), Anevski (U.S. Patent No. 6,388,122), and Zhang (WO 01/52838) based upon the results listed in Table I located on pages 16 and 17 of the amendment of November 28, 2005. It is noted that the results are not in the form of a 37 CFR 1.132 declaration. As disclosed in the remarks, the Bristol Myers-Squibb composition of Table 1 may or may not be made by the method of Agharkar (U.S. Patent No. 5,504,102). Accordingly, the Bristol Myers-Squibb composition column of Table 1 is not considered to be pertinent. The IVAX's composition is urged to be related to U.S. Patent No. 6,306,894. However, the claims were not rejected under 35 U.S.C. 102(B) or under 35 U.S.C. 103(a) in view of U.S. Patent No. 6,306,894. Accordingly, IVAX's composition column of Table 1 is also not considered to be pertinent. The table is silent with regard to Anevski (U.S. Patent No. 6,388,122), and Zhang (WO 01/52838). It is also silent as to the precise steps used in Serial No. 10/626,501. As such, the showing does not demonstrate a difference between the claimed composition and the composition of each of Agharkar (U.S. Patent

No. 5,504,102), Anevski (U.S. Patent No. 6,388,122), and Zhang (WO 01/52838).

Accordingly, the claims are considered to read on each of Agharkar (U.S. Patent No. 5,504,102), Anevski (U.S. Patent No. 6,388,122), and Zhang (WO 01/52838).

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

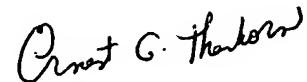
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to E. Therkorn at telephone number (571) 272-1149. The official fax number is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



**Ernest G. Therkorn**  
**Primary Examiner**  
**Art Unit 1723**

EGT

December 7, 2005